

**Claims:**

1. A recognition molecule, **characterized in that** it comprises an amino acid sequence which contains
  - (i) the amino acid sequence SEQ ID NO. 1 or 2 and
  - (ii) the amino acid sequence SEQ ID NO. 3 or 4 and
  - (iii) the amino acid sequence SEQ ID NO. 5 or 6and  
specifically binds the glycosylated MUC1 tumor epitope.
2. The recognition molecule according to claim 1, **characterized in that** it comprises an amino acid sequence which contains the amino acid sequences SEQ ID NO. 1 and SEQ ID NO. 3 and SEQ ID NO. 5 and specifically binds the glycosylated MUC1 tumor epitope.
3. The recognition molecule according to claim 1, **characterized in that** it comprises an amino acid sequence which contains the amino acid sequences SEQ ID NO. 2 and SEQ ID NO. 4 and SEQ ID NO. 6 and specifically binds the glycosylated MUC1 tumor epitope.
4. The recognition molecule according to any of claims 1 to 3, **characterized in that** it further comprises an amino acid sequence which contains
  - (i) the amino acid sequence SEQ ID NO. 7 or 8 and
  - (ii) the amino acid sequence SEQ ID NO. 9 or 10 and
  - (iii) the amino acid sequence SEQ ID NO. 11 or 12and  
specifically binds the glycosylated MUC1 tumor epitope.
5. The recognition molecule according to claim 2, **characterized in that** it further comprises an amino acid se-

quence which contains the amino acid sequences SEQ ID NO. 7 and SEQ ID NO. 9 and SEQ ID NO. 11 and specifically binds the glycosylated MUC1 tumor epitope.

6. The recognition molecule according to claim 3, **characterized in that** it further comprises an amino acid sequence which contains the amino acid sequences SEQ ID NO. 8 and SEQ ID NO. 10 and SEQ ID NO. 12 and specifically binds the glycosylated MUC1 tumor epitope.
7. The recognition molecule according to any of claims 1 to 6, **characterized in that** it is modified by mutation, deletion and/or insertion in at least one of sequences SEQ ID Nos. 1 to 12 and specifically binds the glycosylated MUC1 tumor epitope.
8. The recognition molecule according to any of claims 1 to 7, **characterized in that** at least one amino acid of at least one sequence in accordance with SEQ ID Nos. 1 to 12 is replaced by an amino acid having analogous physicochemical properties, and that the recognition molecule specifically binds the glycosylated MUC1 tumor epitope.
9. The recognition molecule according to any of claims 1 to 8, **characterized in that** at least one sequence of sequences SEQ ID NO. 1 or 2 is replaced by an equivalent canonical structure variant in accordance with SEQ ID Nos. 13 to 20 and/or at least one sequence of sequences SEQ ID NO. 3 or 4 is replaced by an equivalent canonical structure variant in accordance with SEQ ID Nos. 21 to 23 and/or at least one sequence in accordance with SEQ ID NO. 7 or 8 is replaced by an equivalent canonical structure variant in accordance with SEQ ID Nos. 24 to 29 and/or at least one sequence of sequences SEQ ID NO. 11 or 12 is replaced by an equivalent

lent canonical structure variant in accordance with SEQ ID No. 30 or 31 and the recognition molecule specifically binds the glycosylated MUC1 tumor epitope.

10. The recognition molecule according to any of claims 1 to 9, **characterized in that** it comprises amino acid sequences having at least a homology of at least 60%, preferably 70%, more preferably 80%, especially preferably 90%, with respect to the sequences SEQ ID Nos. 1 to 12, said recognition molecule specifically binding the glycosylated MUC1 tumor epitope.
11. The recognition molecule according to any of claims 1 to 10, **characterized in that** it further comprises framework sequences separating, enclosing and/or flanking said amino acid sequences.
12. The recognition molecule according to claim 11, **characterized in that** the framework sequences are selected from the group comprising the immunoglobulin superfamily, protease inhibitors, lectins, helix bundle proteins and/or lipocalins.
13. The recognition molecule according to claim 11 or 12, **characterized in that** the framework sequences are antibody framework sequences.
14. The recognition molecule according to claim 13, **characterized in that** the antibody framework sequences for the recognition molecule according to claim 1, 2 or 3 are sequences of the variable heavy chain,  $V_H$ , and the antibody framework sequences for the additional sequences of the recognition molecule according to claim 4, 5 or 6 are sequences of the variable light chain,  $V_L$ .

15. The recognition molecule according to claim 13 or 14, **characterized in that** the antibody framework sequences are of murine origin.
16. The recognition molecule according to claim 13 or 14, **characterized in that** the antibody framework sequences are of human origin.
17. The recognition molecule according to any of claims 13 to 16, **characterized in that** the antibody framework sequences are derived from framework sequences or combinations of framework sequences in accordance with claim 15 or 16.
18. The recognition molecule according to any of claims 11 to 17, **characterized in that** the antibody framework sequences
  - a) FRH1, FRH2, FRH3 and FRH4 for the variable heavy chain  $V_H$  are the following amino acid sequences, the amino acid position corresponding to the numbering according to Kabat:

for FRH1 in position	1	E
	2	V
	3	K
	4	L
	5	V
	6	E
	7	S
	8	G
	9	G
	10	G
	11	L
	12	V
	13	Q

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	14	P
	15	G
	16	G
	17	S
	18	M
	19	K
	20	L
	21	S
	22	C
	23	A or V
	24	A, V, S or T
	25	S
	26	G
	27	Y, F, S or D
	28	T
	29	F, L or I
	30	S
for FRH2 in position	36	W
	37	V
	38	R
	39	Q
	40	S
	41	P
	42	E
	43	K
	44	G
	45	L
	46	E
	47	W
	48	V
	49	A
for FRH3 in position	66	R

	67	F
	68	T
	69	I
	70	S
	71	R
	72	D
	73	D or V
	74	S
	75	K
	76	S
	77	S
	78	V
	79	Y or S
	80	L
	81	Q
	82	M
	82a	N
	82b	N
	82c	L
	83	R
	84	A or V
	85	E
	86	D
	87	T
	88	G
	89	I
	90	Y
	91	Y
	92	C
	93	T
	94	R, G, N, K or S
for FRH4 in position	103	W

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104	G
105	Q
106	G
107	T
108	T
109	L
110	T
111	V
112	S
113	S or A

b) FRL1, FRL2, FRL3 and FRL4 for the variable light chain  $V_L$  are the following amino acid sequences, the amino acid position corresponding to the numbering according to Kabat:

for FRL1 in position	1	D
	2	I, V or L
	3	V
	4	M or L
	5	T
	6	Q
	7	T or A
	8	P or A
	9	L or F
	10	S
	11	L or N
	12	P
	13	V
	14	S or T
	15	L
	16	G
	17	D or T
	18	Q or S

	19	A
	20	S
	21	I
	22	S
	23	C
for FRL2 in position	35	W
	36	Y
	37	L
	38	Q
	39	K
	40	P
	41	G
	42	Q or L
	43	S
	44	P
	45	K or Q
	46	L
	47	L
	48	I or V
	49	Y
for FRL3 in position	57	G
	58	V
	59	P
	60	D
	61	R
	62	F
	63	S
	64	G or S
	65	S
	66	G
	67	S
	68	G



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	69	T
	70	D
	71	F
	72	T
	73	L
	74	K or R
	75	I
	76	S
	77	R
	78	V
	79	E
	80	A
	81	E
	82	D
	83	L or V
	84	G
	85	V
	86	Y
	87	Y
	88	C
for FRL4 in position	98	F
	99	G
	100	G or D
	101	G
	102	T
	103	K
	104	L
	105	E
	106	I or L
	106a	K
	107	R
	108	A

19. The recognition molecule according to any of claims 1 to 18, **characterized in that** the recognition molecule comprises a combination of sequences SEQ ID Nos. 32 and 34 or humanized variants of said sequences.
20. The recognition molecule according to any of claims 1 to 18, **characterized in that** the recognition molecule comprises a combination of sequences SEQ ID Nos. 33 and 35 or humanized variants of said sequences.
21. The recognition molecule according to any of claims 1 to 20, **characterized in that** the variable heavy chain  $V_H$  and the variable light chain  $V_L$  are located on different polypeptide chains.
22. The recognition molecule according to any of claims 1 to 20, **characterized in that** the variable heavy chain  $V_H$  and the variable light chain  $V_L$  are directly linked to each other in a fusion protein.
23. The recognition molecule according to any of claims 1 to 20, **characterized in that** the chains in the fusion protein are linked via a linker.
24. The recognition molecule according to claim 23, **characterized in that** the linker consists of 1 to 9 amino acids.
25. The recognition molecule according to any of claims 1 to 24, **characterized in that** it is derived from an immunoglobulin.
26. The recognition molecule according to claim 25, **characterized in that** it comprises a single-chain antibody fragment, a multibody, a Fab fragment, a fusion protein of an antibody fragment with peptides or proteins

and/or an immunoglobulin of the IgG, IgM, IgA, IgE, IgD isotypes and/or subclasses thereof.

27. The recognition molecule according to claim 26, **characterized in that** it comprises a murine, chimerized, humanized, human, partially human antibody or antibody fragment.
28. The recognition molecule according to claim 27, **characterized in that** it comprises at least one sequence in accordance with SEQ ID Nos. 36 to 47, SEQ ID Nos. 60, 62, 64, 66 or 68 or humanized variants of said sequences.
29. The recognition molecule according to claim 27, **characterized in that** it comprises at least one sequence in accordance with SEQ ID Nos. 48 to 59, SEQ ID Nos. 61, 63, 65, 67 or 69 or humanized variants of said sequences.
30. The recognition molecule according to any of claims 1 to 29, **characterized in that** the recognition molecule additionally comprises at least one His-tag, myc-tag, high-lysine sequences and/or multimerization sequences.
31. A construct comprising the recognition molecules according to any of the claims 1 to 30, **characterized in that** the recognition molecules are fused, chemically coupled or non-covalently associated with accessory sequences and/or structures.
32. The construct according to claim 31, **characterized in that** the recognition molecules are fused, chemically coupled, covalently or non-covalently associated with (i) immunoglobulin domains of various species, (ii) enzyme molecules, (iii) interaction domains, (iv) domains

for stabilization, (v) signal sequences, (vi) fluorescent dyes, (vii) toxins, (viii) catalytic antibodies, (ix) one or more antibodies or antibody fragments with different specificity, (x) cytolytic components, (xi) immunomodulators, (xii) immunoeffectors, (xiii) MHC class I or class II antigens, (xiv) chelating agents for radioactive labelling, (xv) radioisotopes, (xvi) liposomes, (xvii) transmembrane domains, (xviii) viruses and/or (xix) cells.

33. The construct according to claim 32, **characterized in that** the cells are macrophages.
34. An isolated nucleic acid molecule comprising nucleic acid sequences encoding the amino acid sequence of at least one recognition molecule according to claims 1 to 30 or a construct according to any of claims 31 to 33.
35. The nucleic acid molecule according to claim 34, **characterized in that** it is a genomic DNA, a cDNA and/or an RNA.
36. An expression cassette or vector comprising a nucleic acid molecule according to any of claims 34 or 35 and a promoter operatively linked with the nucleic acid.
37. A virus comprising at least one vector or expression cassette according to claim 36.
38. A host cell comprising at least one vector or expression cassette according to claim 36.
39. The host cell according to claim 38, **characterized in that** it is a prokaryotic or eukaryotic cell.

40. The host cell according to claim 39, **characterized in that** it is a bacterial, yeast, plant, insect and/or mammal cell.
41. The host cell according to claim 40, **characterized in that** the mammal cell is a hamster, mouse and/or human cell.
42. The host cell according to any of claims 38 to 41, **characterized in that** the host cell is *E. coli*, *S. cerevisiae*, *P. pastoris*, *D. melanogaster*, CHO-K1, CHOdhr-, NS0, SP2/0, HEK 293, COS-1, COS-7, PER.C6, Namalwa or K562.
43. The host cell according to claim 41, **characterized in that** the host cell is an effector cell.
44. An organism comprising at least one host cell according to claims 38 to 42.
45. The organism according to claim 44, **characterized in that** the organism is a vegetable or an animal transgenic organism.
46. A composition comprising at least one
  - (i) recognition molecule according to any of claims 1 to 30; and/or
  - (ii) construct according to any of claims 31 to 33; and/or
  - (iii) nucleic acid molecule according to claim 34 or 35.
47. The composition according to claim 46, **characterized in that** the composition is a pharmaceutical composition, optionally with a pharmaceutically tolerable carrier and/or adjuvant.

48. The composition according to any of claims 46 or 47, **characterized in that** the composition comprises:
- (i) a radiolabelled recognition molecule according to any of claims 1 to 30 and/or
  - (ii) a non-labelled recognition molecule according to any of claims 1 to 30.
49. The composition according to claim 48, **characterized in that** the recognition molecule comprises a sequence according to any of claims 19, 20, 28 or 29.
50. The composition according to claim 46 or 47, **characterized in that** the composition is a vaccine composition.
51. A method for the production of recognition molecules or constructs according to any of claims 1 to 33, comprising:
- (i) incorporating one or more nucleic acid molecules according to any of claims 34 or 35 and/or an expression cassette or a vector according to claim 36 in a virus according to claim 37 or in a host cell according to any of claims 38 to 43;
  - (ii) culturing the host cells or viruses under suitable conditions; and
  - (iii) obtaining the recognition molecule or construct, the effector cell bearing the recognition molecule or construct, or the virus, which specifically recognize the glycosylated MUC1 tumor epitope.
52. A method for the production of a composition according to any of claims 46 to 50, comprising a combination of a recognition molecule according to any of claims 1 to 30, a construct according to any of claims 31 to 33, a nucleic acid according to claim 34 or 35 and/or a vec-

tor according to claim 36, together with a pharmaceutically suitable carrier, a solution and/or an adjuvant.

53. The method according to claim 52, additionally comprising the step of formulating the composition in a pharmaceutically tolerable and/or effective form.
54. Use of a recognition molecule according to any of claims 1 to 30, a construct according to any of claims 31 to 33, a nucleic acid molecule according to claim 34 or 35, a vector according to claim 36, a virus according to claim 37, a host cell according to any of claims 38 to 43, an organism according to claim 44 or 45 and/or a composition according to any of claims 46 to 50 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of tumor diseases and/or metastases.
55. The use according to claim 54 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of MUC1-positive tumor diseases and/or metastases.
56. The use according to claim 54 or 55 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of carcinomas and/or metastases.
57. The use according to any of claims 55 or 56 in the prophylaxis, prevention, diagnosis, reduction, therapy, follow-up and/or aftercare of mammary carcinomas, gastrointestinal tumors, including colon carcinomas, stomach carcinomas, large intestine cancer and small intestine cancer, pancreas carcinomas, ovarian carcinomas, lung cancer, liver carcinomas, renal cell carcinomas, multiple myeloma and/or metastases thereof.

58. The use according to any of claims 54 to 57, **characterized in that** the recognition molecule is a non-labelled recognition molecule according to any of claims 1 to 30 or construct according to any of claims 31 to 33.
59. The use according to claim 58, **characterized in that** the recognition molecule is bound to macrophages.
60. The use according to claim 58 or 59, **characterized in that** the recognition molecule comprises a sequence according to any of claims 19, 20, 28 or 29.
61. The use according to any of claims 54 to 57, **characterized in that** the recognition molecule is a radio-labelled recognition molecule according to any of claims 1 to 30 or construct according to any of claims 31 to 33.
62. The use according to claim 61, **characterized in that** the recognition molecules comprise IgG or fragments thereof.
63. The use according to claim 61 or 62, **characterized in that** the recognition molecules comprise multibodies.
64. The use according to any of claims 61 to 63, **characterized in that** the recognition molecule comprises a sequence according to any of claims 19, 20, 28 or 29.
65. The use according to any of claims 54 to 64, **characterized in that** at least one non-labelled recognition molecule according to any of claims 1 to 30 or construct according to any of claims 31 to 33 and at least one labelled recognition molecule according to any of claims 1 to 30 or construct according to any of claims 31 to 33 are used in combination.



66. The use according to claim 65, **characterized in that** at least one recognition molecule comprises a sequence according to any of claims 19, 20, 28 or 29.
67. A method for the production of a diagnostic agent, comprising the steps of claim 51 for the production of recognition molecules specifically binding the glycosylated MUC1 tumor epitope, and comprising the step of formulating the recognition molecules in a diagnostically suitable form.
68. The method according to claim 67, **characterized in that** the recognition molecules are biotinylated, fluorescence-labelled, radioactively labelled, directly labelled via enzyme linking and/or detected via a secondary, appropriately labelled antibody.
69. Use of any of the methods according to claim 67 or 68, **characterized in that** the recognition molecule is employed in the diagnosis of tumor diseases and/or metastases, in the prognosis of tumor diseases and/or in the follow-up of tumor diseases.
70. The use according to claim 69 and/or of the method according to claim 67 or 68 in the diagnosis of MUC1 antigen-bearing tumors and/or metastases.
71. The use according to claim 70, **characterized in that** the tumors are mammary carcinomas, gastrointestinal tumors, including colon carcinomas, stomach carcinomas, large intestine cancer and small intestine cancer, pancreas carcinomas, ovarian carcinomas, liver carcinomas, lung cancer, renal cell carcinomas, multiple myeloma and/or metastases thereof.

72. The use according to any of claims 69 to 71, **characterized in that** at least one recognition molecule is employed in a tissue rapid test for immunohistologic detection.
73. The use according to any of claims 69 to 71, **characterized in that** at least one recognition molecule is employed in a serologic test in a sandwich procedure.
74. The use according to any of claims 69 to 71, **characterized in that** at least one recognition molecule is employed in *in vivo* diagnostics in the form of radioimmuno-diagnostics, PET scan methods and/or immunofluorescence endoscopy.
75. The use according to any of claims 69 to 74, further comprising at least one additional antibody against at least one other tumor antigen.
76. A kit comprising a recognition molecule according to any of claims 1 to 30 and/or a construct according to any of claims 31 to 33.